TCT-19

Randomized Trial of Proximal- vs. Distal Cerebral Protection on Microembolization During Carotid Artery Stenting in Patients with High-risk Lipid Plaque

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Background: Cerebral embolization is the major complication of carotid artery stenting (CAS). Proximal protection has been found to offer a better protection than filter in unselected patients scheduled for CAS. To compare the efficacy of proximal- (MOMA, Invatec, Italy) vs. distal (Filterwire EZ, Boston Scientific, USA) protection in patients with high risk lipid plaque.
Methods: Fifty-three consecutive patients with carotid artery stenosis (>70% if asymptomatic and >50% stenosis if symptomatic by Doppler US) and lipid plaque by CT-angiography (≤50 Hounsfield unit) were randomized to CAS with MOMA (n=26) or Filterwire EZ (n=27). Microembolic signals (MES) were detected by trans-cranial Doppler of the ipsilateral middle cerebral artery in the following 6 phases: 1) lesion wiring 2) Predilation 3) Stent crossing. 4) Stent deployment. 5) Post-dilation and 6) Protection device retrival/deflation. Standard CAS technique and anticoagulation/antiplatelet treatment were used in all patients. Predilation was left at operator's discretion. Carotid Wallstent was used in all cases.
Results: Patient and angiographic target lesion characteristics were not different between the 2 groups. Hounsfield units value was similar in both groups: 31±9 vs. 31±11, p=NS. "High-surgical risk" characteristics were detected in 41% of patients.CAS was successful in all cases. No intolerance to MOMA was detected. Two in-hospital cerebral complications occurred in the Filterwire EZ group (1 retinal embolism and 1 TIA at 48 hours). Number of pts with detectable MES was significantly greater in filter vs. MOMA group in phase 3 to 5 (100% vs. 27%, p=0.000). MES number for each CAS phases are reported in the Table.

	Filterwire EZ	MOMA	p Value
Lesion wiring	20.93±14.2	5.77±9.3	<0.0001
Pre-dilation	8.43±5.1	2.20±5.2	0.26
Stent crossing of the lesion	30.59±30.7	1±2.2	<0.0001
Stent deployment	24.37±15.7	1.46±3.9	<0.0001
Stent post-dilation	20.0±14.7	2.73±6.2	<0.0001
Device retrieval/deflation	3.63±4.5	10.73±10.4	<0.0001
Mean MES /patient	19.64±10.7	4.22±3.5	<0.0001
Total MES	101.7±53.4	22.54±18.8	<0.0001
Predilation performed in 7 pts with Filterwire EZ and 10 pts with MOMA			

Conclusions: CAS with MOMA led to significantly lower MES counts supporting the safety and efficacy of this type of protection even in patients with high risk lipidic plaque.

TCT-20

Neuropsychological Changes Following Carotid Artery Stenting in Asymptomatic Patients

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Aim: To investigate the **changes in neuropsychological performance** following elective carotid artery stenting (CAS) in asymptomatic patients (APs).
Methods: 43 APs (Mean age = 71, *SD* = 8; 65% male) were treated with CAS under cerebral protection (Mean time = 6.4 min, *SD* = 1.2). APs received a total of 47 procedures (4 had staged bilateral CAS) and were assessed at baseline and post-procedure (three months apart) using
Echo-Doppler, CT scan, neurological evaluation, and a comprehensive neuropsychological battery.
Outcomes: Angiographic success was achieved in all procedures; 1 AP suffered a TIA, and another had a fatal hemorrhagic stroke two weeks after index procedure. Mean hospitalization time was 1.2 days (SD = 1.3). Three-month follow-up revealed significant improvement in verbal (RAVLT learning: t_{45} = -4.17, p < .001; RAVLT delayed score: t_{45} = -3.2, p < .001) and visual (ROCF delayed: t_{42} = -3.65, p < .001) memory as well as in executive functions (TMT-B: t_{41} = -3.13, p < .001; WCST: t_{37} = -2.54, p = .015; speed processing: t_{41} = -2.60, p = .013) although no significant differences were found on pre- & post-procedural mood scores.
Conclusion: Our results reveal that CAS improves cognitive performance in supposedly asymptomatic patients, suggesting that such "asymptomatic" nature may in fact be overlooking at the cognitive profile of this patient population. Including comprehensive cognitive assessment of CAS candidate patients is essential in order to determine procedural outcome.

TCT-21

Percutaneous Transluminal Angioplasty and Stenting of Extracranial Vertebral Artery Stenoses

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Purpose: To evaluate the safety and efficiency of vertebral angioplasty and stenting (VAS) in symptomatic patients.
Material and methods: 97 angioplasties in 91 pts (M:69) mean age 68,2 ± 6,8 years (22-84) left 55. All pts had multivascular diseases: carotid (CA):61, subclavian (SA): 24, coronary:62.... Atheromatous lesions: 95, inflammatory: 2. Mean lesion length: 9,6 +/- 2,8 mm. Mean % stenosis 83.1 ± 7.8, mean arterial diameter : 4,8 ± 0,6 mm (4-6). 89 lesions at VO segment (ostium), 6 at V1 and 2 at V2 segments. Indications for angioplasty: dizziness (91), bilateral weakness (11), visual changes (11), diplopia (10), drop attacks (19), TIA (12), ataxia (5). A protection device (filter) used in 8 pts. 17 SA angioplasties performed at the same time of VAS, 7 CA. All angioplasties performed by femoral approach, 4 by brachial approaches after failure of femoral approach. (2 successes).
Results: Technical success 95/97 (98%). Defined. 6 lesions treated by angioplasty alone: 3 VO (first 3 pts. 2 V1, 1 V2 lesion). 1 pt (inflammatory disease) treated by cutting balloon alone. 84 lesions treated with stents (direct stenting: 69). Peripheral balloon expandable stents (n=19), self expandable stents (n=4 for 3 V1 and one V2 lesions). 65 coronary stents (11 DES). 1 pt developed a TIA during the procedure. No neurological complications at 30 days Clinical success 89/91 (98%)
Post-procedure arterial diameter: 4,55 ± 0,8 mm (4-6). Mean residual stenosis 2,2 ± 3,5 %.
In 8 pts treated with protection devices, visible debris removed in 6 (4 Filterwire, 2 Fibernet) with the same amount of debris as during Carotid Stenting) 6 pts (9%) developed symptomatic restenosis during the follow-up (mean: 32.2±28.8 months). 3 after PTA alone, 1 after PTA and stent (1 occlusion treated medically, 5 stenoses successfully treated with PTA). No restenosis after DES implantation at 1 year.
Conclusion: VAS can be performed safely and effectively with a high technical success rate, a low complication rate, a low restenosis rate and a durable clinical success in patients with symptomatic VA stenosis. Stents seem to improve immediate and long-term results. The role of protection devices has to be discussed.

TCT-22

Mechanical Embolectomy For Large Vessel Ischemic Strokes

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Introduction: Large vessel (proximal middle cerebral, internal carotid and basilar arteries) acute ischemic stroke has a poor outcome with reported mortalities of 30 -90%. The survivors are often left with significant neurological impairment. Intra-venous thrombolysis is often contra-indicated and if given, usually ineffective. Mechanical embolectomy is an option in these patients and may be performed by an interventional cardiologist experienced in carotid interventions.
Method: From January 2007 to September 2009 consecutive stroke patients were assessed by the stroke physician and, if eligible, referred for possible mechanical embolectomy using the Merci Retriever (Concentric Medical, Mountain View, California, USA). Intra-arterial thrombolysis was permitted. All procedures were done by a single cardiologist. Patient information, procedural characteristics and clinical outcomes at 90 days were collected by retrospective chart review.
Results: A total of 22 patients (mean age 66.9 years) were referred for emergency cerebral angiography with 17 undergoing mechanical embolectomy. Intra-arterial thrombolysis was administered in nine patients The mean National Institute of Health Stroke Scale (NIHSS) score was 20.1 and the mean stroke duration was 284 minutes. Recanalization was successful in 15 (88%) patients. Of these 15 patients ten (59%) had a good outcome (modified Rankin Score ≤ 2 @ 90 days) and 2 died (mortality 13%). Three patients had significant intra-cerebral hemorrhage (1 died and 2 had a good outcome). There were no other major adverse events. Of the 7 patients where recanalization failed, 3 died (mortality 43%) and only 1 had a good outcome (14%).
Conclusions: For patients with large vessel occlusion strokes where intra-venous thrombolysis was either contra-indicated or had failed, mechanical embolectomy performed by an interventional cardiologist had a high recanalization rate with an acceptable clinical outcome and safety profile.

TCT-23

Endovascular Treatment of Thoracic Aortic Disease: Eleven Years Follow-Up

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Background: The aim of this perspective study is to investigate efficacy and long-term results of stent graft treatment for diseases of descending thoracic aorta.
Methods: From March 1999 to May 2010, 184 patients (156 male and 28 female, mean age 62±14 years) were enrolled. They were divided into 3 groups: aneurysms (65, Group A: 9 with acute rupture), post-traumatic lesions (57, Group B: 38 acute and 19 chronic) and complicated type B dissection (62, Group C: 43 acute and 19 chronic). All patients underwent CT scan and angiography as preoperative assessment.
Results: An optimal deployment with exclusion of the aneurysm, repair of the aortic lesions in post-traumatic and closure of the primary entry tear in dissection was achieved acutely in 98.4% (184/187) of the patients that were discharged in good conditions within 5 days. No spinal cord injuries were observed. The follow-up (average 52 months, range 1 to 134), performed with serial CT scans, was 100% complete. Stent graft-related complications were detected in 5.4% (10/184) of the patients: Two re-lining for symptomatic type III endoleak in Group A (3.1%). Two asymptomatic connecting bar rupture in Group B (3.5%). Four distal asymptomatic retrograde blood flow inside the false lumen in Group C (6.4%) and 2 retrograde type A dissection in the same group (3.2%) successfully treated by conventional surgery approach. Only in 2 patients in Group C (3.2%) a proximal new entry tear was detected during the follow-up successfully treated by a second endoprosthesis. A total of 5 hospital deaths resulted in an overall operative mortality of 2.7%. Ten patients (5.4%) died during the follow-up: Four of them for co-morbidities (2.2%), whereas 6 patients (3.2%) for disease progression.
Conclusions: Endovascular treatment of thoracic aortic diseases, even in the acute phase, may represent a valid option with a low mortality rate. Moreover, the efficacy is proved in the long-term follow-up.

TCT-24

A New Protection Device: the Fibernet. First Human Use in Carotid, Renal and Peripheral Interventions

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Background: It is now clear that atheroemboli are the rule in any intervention in atherosclerotic disease and seems the root cause of any procedural complications. Embolic Protection Devices (EPD) are widely used in carotid and several reports pointed out their role in other peripheral procedures (renal, leg,vertebral arteries). However current EPD have significant limitations, which may be addressed by a new EPD the Fibernet ™ (Lumen Biomedical Inc., Plymouth Mass.)
Methods: The system consists of a 3 dimensional expandable filter made of unique fibers, which expand radially to fill the lumen, mounted onto a 190 cm long 0.014 wire. No delivery sheath required. Low crossing profile (1,7 - 2,9 F). Retrieval catheter with focal suction during device removal allowing meticulous cleaning of the vessel. The filter can fill vessels from 1,75 to 7 mm and capture particles as small as 40 microns without compromising the flow.
Results: We performed:
- 68 carotid Angioplasty Stenting. Technical success 98 %. 30-day complications: 1 minor stroke (1,5%). Debris analysis done in 34 Fibernet procedures and compared with 14 other filters. Visible

debris retrieved in all cases with Fibernet, 43% with other filters. Mean debris surface area: Fibernet 63,8 mm², other filters 12,2 mm². Number of particles < 100µ: 4976 with Fibernet, 2752 with other filters.
-12 renal angioplasties. Technical success: 100%. No complication. All samples visually contained significant emboli. Mean debris surface area: 106 mm², debris in the filter: 24 mm²). Mean number of particles 28-60µ: 2136 +/- 776. and > 60µ: 5918 +/- 1362. At 6 month follow-up no deterioration of the renal function.
-2 vertebral angioplasties. Visible debris removed in the 2 patients. Mean debris area: 184 mm². (aspirated debris: 114 mm², debris in the filter 70 mm²) (Comparable results as in carotid angioplasty).
-3 femoropopliteal angioplasties for chronic occlusion. Visible debris removed in the 3 patients. 2 filters totally blocked. Mean debris area: 191 mm²
Conclusion: The Fibernet EPD is easy to use and very efficient. Visible debris are removed in all patients. It allows for capture of particles < 100µ without compromising the flow. It could be used in any vessels.

ORAL

Chronic Total Occlusions

143C

Wednesday, September 22, 2010, 3:30 pm – 5:30 pm

(Abstract Nos 25-32)

TCT-25

Percutaneous Coronary Angioplasty of Chronic Total Occlusion. Is There a Learning Curve ?

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Purpose: Percutaneous coronary angioplasty (PCI) of Coronary Chronic Total Occlusions (CTO) is still associated with a reduced success rate. Lesion- and patient- related factors of failure are well known, but the influence of operator experience influence has been less described. The purpose of this abstract is to describe the influence of the operator and known predictive factors on the success rate of CTO PCI (European CTO club definition) treated by several operators in our institution.
Methods: The study included 1,000 consecutive CTO PCI performed between Jan2004 and Dec 2009 by 13 operators. In order to assess the learning curve, an index of individual operator experience during the study was defined as 1 for the first 50 cases, 2 for next fifty, up to 6 for operators with > 250 cases. PCI performed by the 2 main operators were compared with 11 others.
Results: A multivariate logistic regression analysis was performed in the whole population using all factors with a p value <0.2 by univariate analysis. Previous CABG (0R 0.44; p= 0.015), no visible stump (OR 0.61; p= 0.031), calcifications (0-3)(OR 0.78; p= 0.009) and the occlusion length (OR 0.98; p= 0.000; 2% failure for each mm of occlusion length) were found to be independent predictors of failure. The operator's experience was a predictor of success (OR 1.24; p= 0.002) but the year of treatment in the whole group was not. Here are the success rates and predictors value in patients treated by 2 main operators and others.

	2 main operators	Other operators (n=11)	p
CTO's n=	542	458	
Success rate (%)	72.2	66.6	0.013
Experience	4.17 ± 1.58	1.35 ± 0.55	0.000
Previous CABG (%)	10.0	4.4	0.004
No visible stump (%)	29.2	18.3	0.011
Calcifications (0-3)	1.07 ± 1.02	0.96 ± 1.0	0.072
Occlusion length (mm)	23.2 ± 18.0	19.8 ± 15.9	0.039

Conclusion: Individual experience of the operator but not of the whole team is a strong predictor of CTO PCI success despite a higher incidence of predictors of failure.

TCT-26

The Impact of Percutaneous Coronary Intervention for CTO Lesions and Contrast Media on Renal Function

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Background: Improvements in the technique and success rates of percutaneous coronary intervention (PCI) for chronic total occlusions (CTOs) have resulted in an increase in the complexity of PCI. Contrast media volume, one of the major risk factors for contrast-induced nephropathy (CIN), represents an extremely important concern in the management of patients with CTO lesions. The aim of this study was to evaluate the impact of CTO procedures and contrast media use on renal function.
Methods: We evaluated in-hospital, procedural outcomes related to renal function in 425 consecutive patients who underwent PCI for CTOs of > 3 months in duration between April 2006 and March 2009 compared to the non-CTO control group (n=XXXX), reporting baseline and 48 h postprocedural creatinine levels. CIN is defined as an absolute (≥0.5 mg/dl) or relative (≥25%) increase in serum creatinine levels compared to baseline values after exposure to contrast media in the absence of alternative explanations for renal impairment.
Results: In 425 consecutive CTO patients (mean age, 65.5 ± 11.0 yrs; 83.3% male), the average total amount of contrast media administered was significantly higher than non-CTO control group (328.6 ± 163.1 ml vs. 194.6± 112.7 ml, p<0.0001) . Serum creatinine level after the procedure was also significantly higher in CTO patient than in non-CTO patient (0.95 ± 0.28 mg/dl vs. 0.91 ± 0.33 mg/dl, p=0.05). CIN occurred in 10.8% (46/425) of the CTO group and 6.7% (57/850) of the non-CTO group (p=0.02). Patients who developed CIN were older (70.0 ± 9.9 yrs. vs. 65.0 ± 10.9 yrs., p=0.0016), had longer fluoroscopy time (75.2±47.0 min vs. 51.7±35.0 min, p=0.0001) and received a higher amount of contrast media (424±212 ml vs. 326±151 ml, p<0.00001) than those who did not develop CIN in the CTO group. Multivariate logistic regression analysis revealed that significant predictors of CIN were age (OR 2.8, 95%CI 1.025-1.140) and contrast volume (OR 3.0, 95%CI 1.004-1.006). Of 46 patients who developed CIN, 38 patients (82.6%) experienced a recovery of their renal function at 1 month, with no patients requiring dialysis during that time.
Conclusions: The incidence of CIN following CTO-PCI was significantly higher than that following Non-CTO-PCI. To prevent CIN, careful attention should be paid to identifying patients at risk for the condition and minimizing the amount of contrast media used in these patients during CTO procedures.

TCT-27

Improved Cardiac Survival and Quality of Life after Successful Percutaneous Recanalisation of Coronary Artery Chronic Total Occlusions: a Single-Centre Experience

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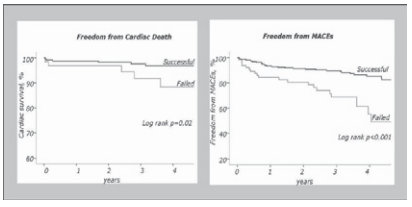
Background: We sought to compare the effects of a successful chronic total occlusion (CTO) recanalisation on long-term cardiac survival and angina-related quality of life compared to failed procedure.
Methods: CTO was defined as a native coronary artery occlusion with duration >3 months and TIMI flow 0. Primary end-points were cardiac death and MACEs, defined as cardiac death, MI and target vessel revascularisation at follow-up. The SAQ-UK questionnaire was used to assess angina-related quality of life before and after CTO recanalisation procedure.
Results: Among 302 consecutive patients, 78% underwent successful CTO recanalisation while in 22% patients the procedure failed. Multivariate predictors of unsuccessful procedure were moderate-severe vessel calcification (OR 3.61;95%CI1.53-8.52;p<0.01), CTO length >20 mm (OR 2.64;95%CI1.18-5.88;p=0.01) and CTO duration >12 months (OR 3.01;95%CI1.15-6.91;p=0.02). Median follow-up was 3.4 years, during which 15 patients had a cardiac death. When compared with successful procedure, failed CTO recanalisation was associated with a significant higher risk of cardiac death (HR 5.01;95%CI1.29-19.4; Log-rank p=0.02), and MACEs (HR 4.7;95%CI2.37-9.6; Log-rank p<0.001). These results were confirmed by Cox proportional hazard analysis for survival, after adjustement for age, previous MI and LV ejection fraction. By SAQ-UK questionnaires, patients with successful CTO recanalisation experienced fewer physical activity limitations, rarer angina episodes and higher quality of life at longer follow-up (all p<0.05) when compared to patients with failed procedure.



Conclusions: Successful percutaneous CTO recanalisation improved long-term cardiac survival, reduced major adverse cardiac events and improved the angina-related quality of life compared to failed procedure.

TCT-28

Long-Term Clinical Safety and Efficacy of Drug-Eluting Stents for the Treatment of Chronic Total Occlusions: Report from a Multi-National 763 Patient Registry

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Background: Drug-eluting stents (DES) are widely used in the treatment of CTOs, even though long-term safety and efficacy data are currently lacking.
Methods: Between 2002 and 2009, 763 patients with 795 CTO were treated with DES at four tertiary care centers in the US, the UK, Italy and South Korea. Long term follow-up was obtained for all patients by office visit or telephone interview. The primary clinical endpoint was target vessel failure (TVF, composite of death, myocardial infarction [MI] and target vessel revascularization [TVR]. The primary safety endpoint was definite/probable stent thrombosis up to five-year follow-up.
Results: Mean age was 61±11 years, 28% of patients had diabetes mellitus, 36% had prior myocardial infarction and 12.7% had prior CABG, mean LVEF was 54±10%. The CTO location was the left anterior descending coronary artery in 37% of patients, circumflex coronary artery in 21%, and right coronary artery in 42%. The mean lesion length was 24±16 mm; a mean of 1.9±0.9 stents were implanted per patient; mean stent length was 48±24 mm. Sirolimus-eluting stents (SES) were used in 73% of patients, and paclitaxel-eluting stents (PES) in 27%. The median follow-up duration was 2.8 years (interquartile range 2.0-3.8 years). Kaplan-Meier estimates for five-year all-cause death, MI, TVR and TVF were 5.6%, 2.5%, 17.4%, and 24.0%, respectively (Figure). Of note, there was a linear rate of late (>1 year) TVR events (2.1% per annum). At five years, 9 patients (1.5%) had a definite/probable stent thrombosis of which 5 (0.8%) occurred after one year.